REMARKS

The pending final Office Action addresses and rejects claims 1-33.

Amendments to the Claims

Independent claims 1, 22, and 29 are amended to include the limitations of claims 5 and 6, and in particular to recite a flexible membrane that is disposed across an opening formed in the catheter. Claim 5 is canceled, and claim 6 is amended to remove the limitations added to claim 1 and to depend from claim 1. Claims 3, 4, 17, 21, 28, and 30 are amended to correspond to amended claims 1, 22, and 29. No new matter is added.

Rejections Pursuant to 35 U.S.C. §102

Claims 1-5, 9-10, 21-23, and 28-30 are rejected pursuant to 35 U.S.C. §102(b) as being anticipated by U.S. Patent No. 4,928,693 of Goodin et al. In the Advisory Action, the Examiner argues that "Goodin et al. teaches a pressure monitor catheter wherein the entire device is comprised of an elongated flexible plastic tubular member (claim 1)[,] a sealed lumen filled with an incompressible saline fluid (20) extending between and in contact with a pressure sensitive component comprising a flexible membrane (14) which is the distal end of the device." The Examiner refers to Col. 4, lines 11-29, which discloses that the catheter tip (14) responds to or measures pressure.

The Examiner continues to ignore the limitations of independent claims 1, 22, and 29. A prior art reference cannot anticipate a claimed invention unless it teaches each and every limitation of the claim. Independent claims 1, 22, and 29 each specifically require a catheter having a sealed lumen that extends between a flexible membrane disposed across an opening in the catheter, and a pressure sensor.

First, Goodin does not teach a catheter having a pressure sensor. To the contrary, it appears that the pressure sensor is part of external measuring equipment, and does not form part of the catheter. See, e.g., Col. 4, lines 22-23, which state that the blood pressure is "transmitted through the fluid to the proximal end 16 of the catheter, and from there to the blood pressure measuring equipment . . . ." (Col. 4, lines 22-23.)

Moreover, the Examiner improperly concludes that the blood pressure measuring lumen (20) of Goodin is sealed, and that the distal end (14) is a flexible membrane. The Examiner has once again failed to point to any such teachings in Goodin. The Examiner merely refers to Col. 4, lines 11-29, which state that "the blood pressure measuring lumen 20 will be filled with an incompressible fluid, e.g., saline so that the blood pressure existing at the distal end of the catheter will be transmitted through the fluid to the proximal end 16 of the catheter, and from there to the blood pressure measuring equipment (not shown)." This language, as well as the remainder of Goodin, does not indicate whether the lumen is sealed, or whether the distal end (14) is a flexible membrane that is disposed across an opening in the catheter.

It appears that the Examiner is relying upon inherency to reject the pending claims. While the inherent disclosures of a prior art reference may be relied upon to reject the claims under 35 U.S.C. §102, "[t]he fact that a certain result or characteristic may occur or be present in the prior art is not sufficient to establish the inherency of that result or characteristic." M.P.E.P. 2112(IV). "To establish inherency, the extrinsic evidence 'must make clear that the missing descriptive matter is necessarily present in the thing described in the reference, and that it would be so recognized by persons of ordinary skill. Inherency, however, may not be established by probabilities or possibilities." *In re Robertson*, 169 F.3d 743, 745 (Fed. Cir. 1999). Goodin does not make it clear that the missing subject matter, namely the sealed lumen and the flexible membrane, is necessarily present and would be so recognized by persons or ordinary skill in the art. To the contrary, Goodin appears to indicate that the lumen is not sealed, and thus does not include any type of flexible membrane. At Col. 2, lines 50-57, Goodin states that:

> Alternatively, the catheter may include two blood pressure measuring lumens, one exiting the distal end of the catheter and the other ending proximally a predetermined distance from the distal end and with a port extending through the wall of the catheter in fluid communication with the shorter lumen. Readings can be simultaneously taken through both lumens without moving the catheter.

While this passage is directed to an alternative embodiment, in this embodiment neither lumen is sealed. Goodin makes it clear that first lumen *exits* the distal end, and the second shorter lumen has a port *extending through* the wall of the catheter. Readings are still taken through the open lumens. Based on

this language, a person having ordinary skill in the art could conclude that lumen (20) of the first embodiment is likewise open and is not sealed. While Col. 4, lines 11-29 of Goodin explains that the lumen can be filled with an incompressible fluid, it is possible for the distal end (14) of the lumen to remain open to receive blood flow therethrough. The fluid could be added during the procedure to eliminate the need for the blood to flow through the entire length of the catheter, and/or to prevent blood from flowing into the external blood pressure measuring equipment. Accordingly, if the Examiner is in fact relying on the theory of inherency to anticipate the claims (which is the only possible basis for the Examiner's rejection), the Examiner has failed to provide a basis in fact and/or technical reasoning to support the determination that the allegedly inherent characteristic *necessarily* flows from the teachings of Goodin. To the contrary, the teachings of Goodin appear to suggest exactly the opposite – namely, that the lumen is open and does not include any type of flexible membrane.

Independent claims 1, 22, and 29, as well as claims 2-5, 9-10, 21, 23, 28, and 30, which depend therefrom, therefore distinguish over Goodin and represent allowable subject matter.

Rejections Pursuant to 35 U.S.C. §103

(1) Claim 6

Claim 6 is rejected pursuant to 35 U.S.C. §103(a) as being obvious over Goodin in view of U.S. Patent No. 5,573,007 of Bobo Sr. The Examiner argues that Goodin discloses the claimed invention, but admits that Goodin fails to teach the use of a flexible membrane disposed across an opening in the sidewall of the catheter. Thus, the Examiner relies on Bobo to teach a pressure monitoring catheter having a membrane disposed across an opening formed in a sidewall, arguing that it would have been obvious to modify Goodin with a flexible membrane of Bobo "because such a modification would provide an opening in the sidewall for fluid entry and a more accurate pressure sensing catheter." Applicants disagree.

At the outset, the Examiner has failed to provide the required motivation for making such a modification. The Examiner merely concludes that providing an opening in the sidewall for fluid entry would provide a more accurate pressure sensing catheter, however it is unclear why such a sidewall

opening would make the catheter more accurate. Goodin already provides a catheter that can obtain accurate pressure readings.

Furthermore, modifying Goodin to include an opening in the sidewall of the catheter with a flexible membrane disposed thereover would render the device inoperative for its intended use. As explained in the Field of the Invention and the Background of the Invention sections of Goodin, the catheter is configured for use conducting transluminal angioplasty or angiography procedures. Thus, the catheter is passed through the artery and placed at the site of a lesion to be treated. If the catheter were modified to measure pressure through an opening in a sidewall of the catheter, the blood pressure in the lumen could not be obtained. In particular, the sidewall of the artery surrounds the catheter and thus would block the opening from responding to the blood pressure within the lumen.

Accordingly, no person having ordinary skill in the art would modify the catheter of Goodin to include a flexible membrane extending across an opening in a sidewall of the catheter, as taught by Bobo, and therefore claim 6 distinguishes over Goodin and Bobo and represents allowable subject matter.

(2) Claims 7, 8, 11-20, 25-27, 31-33

Claims 7, 8, 11-20, 25-27, and 31-33 are rejected pursuant to 35 U.S.C. §103(a) as being obvious over Goodin in view of various references set forth in the Office Action. The Examiner relies on these references to teach various features recited in the dependent claims and not taught by Goodin. As indicated above, Goodin does not teach a catheter having a sealed lumen extending between a flexible membrane disposed across an opening formed in the catheter and a sensor. The various secondary references cited by the Examiner do not remedy these deficiencies of Goodin. Accordingly, claims 7, 8, 11-20, 25-27, and 31-33 distinguish over Goodin and the various secondary references and represent allowable subject matter.

(3) Claims 24 and 30

Claims 24 and 30 are rejected pursuant to 35 U.S.C. §103(a) as being unpatentable over Goodin in view of U.S. Patent No. 5,573,007 of Bobo, Sr. The Examiner relies on Bobo to teach various

features not taught by Goodin. Claims 24 and 30 depend from claim 22 and 29 and are therefore allowable at least because claims 22 and 29 are allowable. Further, the Examiner has failed to establish a prima facie case of obviousness, as noted above, with regard to Goodin and Bobo. Accordingly, claims 24 and 30 distinguish over Goodin and Bobo and represents allowable subject matter.

Conclusion

Applicants submit that all pending claims are now in condition for allowance, and allowance thereof is respectfully requested. The Examiner is encouraged to telephone the undersigned attorney for Applicants if such communication is deemed to expedite prosecution of this application.

Respectfully submitted,

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